

REMARKS

Reconsideration of this application is respectfully requested. Claims 33-42 as amended are presented for consideration.

Status of the Claims

Prior to the present amendment, Claims 33-41 were pending in the instant case. The first Office communication required a restriction of the claims to one of four inventions. At that time, the claims presented for consideration were claims 1-32. Applicant initially elected to prosecute the invention of Group II, namely, claims 8-12, 20, 21 and 25, directed to methods of screening for anti-carcinoma agents that react with a PTK-7 polypeptide. Subsequent to this election, applicant determined that the election of Group IV, namely, claims 15-19 and 29-32 directed to a method of screening, diagnosis and/or prognosis of carcinoma, was preferred. A telephone discussion was conducted with the examiner on July 17, 2008, and on August 8, 2008, a supplemental amendment and response to the restriction requirement was filed. The response to the Restriction Requirement requested a change in the election from Group II to Group IV, and the amendment presented new claims 33-41 corresponding to claims 15-19 and 29-32, that had been canceled as part of the prior response.

Concurrently with this response, applicant has amended the elected claims to endeavor to expedite the prosecution thereof and to focus on the subject matter of present interest herein. Accordingly, the present amendment revises claim 33 and adds new claim 42 that is dependent from claim 35 and defines the capture reagent as an antibody. Further discussion of the claims amendments is presented below.

Claim Rejections – 35 USC §112

Claims 33-41 have been rejected under 35 U.S.C. §112, first paragraph, as lacking written descriptive support in the specification. Applicant has amended the claims in question so that Claim 33 directs itself to carcinoma selected from breast, pancreatic, lung, bladder or kidney cancer or osteosarcoma. Basis for this amendment may be found in the specification as filed, and in original claim 23.

Claim 33 has been also amended to define that the PTK7 polypeptide comprises or consists of the amino acid sequence of SEQ ID NO: 1, or a derivative having at least

70% identity to SEQ ID NO: 1, or a fragment of at least 100 amino acids in length having at least 70% homology over the length of the fragment to SEQ ID NO: 1. Basis for this amendment may be found in the description on pages 5 and 19 of the published PCT specification.

Accordingly, claim 33 is now limited to a specific amino acid sequence or variant thereof having a defined % identity or % homology which can be easily tested by a person skilled in the art. The PTK7 polypeptide of claim 33 is defined as above in order to cover variants such as splice variants, and is, therefore, defined by its sequence and not by its activity.

The Examiner asserts that the specification lacks a showing of activity for polypeptides corresponding to SEQ ID NO: 1, or polypeptides with substitutions, modifications, deletions or insertions that retains the activity of SEQ ID NO: 1. The Examiner refers in this connection, to the publication by *Jung et al.* for a teaching that a protein having this sequence is an inactive kinase, and further states that there is insufficient evidence in the specification of the asserted utility. The examiner cites the articles to *Bowie et al.*, *Burgess et al.* and *Lazar et al.* in support of her position that the uncertainty in activity of close homologs, negates the assumption that such close homology is predictive of like activity.

Jung et al. teaches on page 154, left column, that PTK7 has an extracellular domain with seven immunoglobulin like loops and an inactive catalytic domain of tyrosine kinase. However *Jung et al.* does not teach that PTK7 has no biological activity. In contrast, *Jung et al.* teaches that the findings of expression patterns of splicing variants in testis and hepatoma and colon cancer cells suggest that alternative splicing of PTK7 mRNA may contribute to its diverse function in cell signalling. *Jung et al.* acknowledges on page 162 that the functions of PTK7 and its ligand are still unknown but expression data in developmental stages of spermatogenesis, oogenesis and embryogenesis and in certain cancers demonstrates its involvement in the developmental process and cancer development and metastasis.

It is submitted that the definition of the exact nature of the biological activity of PTK7, including whether it functions as an active or inactive tyrosine kinase, is not necessary for a method of screening or diagnosis comprising detection of PTK7 in order

to meet the requirement of enablement. The present inventors have found an increase of PTK7 expression in certain carcinomas including breast cancer, lung cancer, kidney cancer, bladder cancer and pancreatic cancer, thereby demonstrating at least that PTK7 may be used as a marker for screening or diagnosis of these cancers, as claimed. The skilled artisan would easily be able to carry out the method of screening and/or diagnosis according to the present invention using methods well known in the art and described in the present patent specification for detecting and/or quantifying a PTK7 polypeptide. The skilled person does not require information regarding the activity of PTK7 in order to detect the presence of the polypeptide in a sample. The skilled person need only determine whether a candidate polypeptide has a sequence which falls within the scope of claim 33. The detection of a polypeptide having a defined sequence is easily performed by a person skilled in the art without the need for information regarding the activity of the polypeptide.

Applicants submit that the claims as amended are fully supported by the specification as filed, and the supportive teachings of the extant prior art, and accordingly, withdrawal of this rejection is believed to be in order and is requested.

Claim Rejection – 35 USC §102

Claims 33-41 have been rejected under 35 USC § 102(e) as anticipated by Hess-Stumpp et al. (US 6,780,594). As this rejection may pertain to the claims particularly as presently amended, it is traversed.

Hess-Stumpp relates to a method of diagnosing endometriosis and does not disclose or suggest a method of screening and/or diagnosing breast, pancreatic, lung, bladder or kidney cancer or osteosarcoma as defined in the claims as amended. As the examiner appreciates, the activity of a particular gene or protein in relation to a first condition does not stand as a prediction or teaching that it may or will exhibit the same or a similar activity, or diagnostic, prognostic or therapeutic relevance as to a second condition.

In the present instance the activity of the sequences disclosed in Hess-Stumpp as to endometriosis is not a predictor of like activity with respect to the carcinomas specifically recited herein. Accordingly, the method according to the present invention is

not anticipated by Hess-Stumpp, and withdrawal of this ground of rejection is believed to be in order and is requested.

Claims 33-41 have also been rejected under 35 USC §102(e) as anticipated by Mack et al. (US 7,189,507). As this rejection may pertain to the claims particularly as presently amended, it is traversed.

Mack et al. disclose methods for diagnosing ovarian cancer comprising determining the expression of a gene as set forth in Tables 1-20 of the reference, wherein PTK7 is listed as one of hundreds of other gene sequences. *Mack et al.* do not disclose or suggest a method of screening and/or diagnosis of breast, pancreatic, lung, bladder or kidney cancer or osteosarcoma in a subject, as defined by the claims particularly as amended herein. *Mack et al.* barely if at all, provide the artisan with any suggestion as to the activity and consequent application of particular genes or sequences to given conditions. One is left to extensive and unguided exploration of the *Mack et al.* catalog to choose from among the listed sequences and then conduct exhaustive testing in the hope that activity may be observed. Applicant regards this as undue experimentation, particularly if the reference is to be maintained in rejection of the claims as amended, where a specific group of cancers are defined.

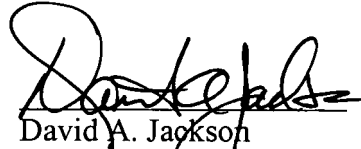
Accordingly, the rejection based on *Mack et al.* as it is applied to the present claims, is believed to be overcome, and reconsideration and withdrawal thereof is requested.

Conclusion

To summarize, therefore, the features of the present method are believed to be more clearly recited in the claims as amended and presented for consideration, and are likewise believed to clearly distinguish the references applied in rejection. Applicants submit that patentable subject matter is clearly defined and that all grounds of rejection have been overcome. Should the Examiner believe that other issues remain for resolution, he is invited to call the undersigned at the number listed below.

In view of the above and foregoing, reconsideration and withdrawal of the outstanding grounds of objection and rejection and early allowance of the claims as amended is believed to be in order and is courteously solicited.

Respectfully submitted,

A handwritten signature in black ink, appearing to read 'David A. Jackson', is written over a horizontal line.

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ENCLOSURES: Request for One (1) Month Extension of Time
Check No. 5219 in the amount of \$130.00